REMARKS

Claims 39, 42, 44 to 48, 62, 69 to 72 and 74 to 76 are pending and under examination.

Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected claims 39, 42, 44 to 46, 48, 62, 69 to 72 and 74 to 76 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,643,296 to Hundertmark et al. (Hundertmark) in view of U.S. Patent No. 4,986,807 to Farr (Farr). The present rejection is substantially identical to the rejection set forth in the December 8, 2008 Office Action except that in the present Office Action Hundertmark is combined with Farr whereas in the earlier office action the rejection was based upon Hundertmark combined with Mueller (U.S. Patent No. 5,053,044). Applicants responded to the December 8, 2008 Office Action in an Amendment and Response filed on February 9, 2009. Applicants respectfully traverse this rejection for the reasons set forth below which are similar to those set forth in the February 9, 2009 Amendment and Response. Further, Applicants will specifically comment on the Examiner's "response to arguments" in paragraphs 7 and 8 of the Office Action.

Claims 39, 62 and 69 are the only independent claims under examination. Applicants submit these claims are allowable for at least the reasons set forth below. Each of the remaining claims depends from one of these independent claims and add further significant limitations which distinguish over the art and are allowable for at least the same reasons as the claim from which they depend.

In paragraph 3 of the Office Action the Examiner states with respect to claim 39 that Hundertmark, in FIG. 11, discloses a method of removing material comprising the steps of: delivering a catheter having a tissue debulking device or cutter 138; deflecting a distal portion of the catheter with respect to a proximal portion of the catheter to expose the cutter, wherein the proximal movement of the catheter through a tortuous blood vessel causes the deflection against an inner cam surface of the catheter. Applicants disagree with the Examiner's characterization of the method disclosed in Hundertmark. However, even if the Examiner has correctly described the method of using the Hundertmark device, the method does not include the steps required by the present claims.

Claim 39 is directed to a method of removing material from a body lumen and recites the step of "deflecting a distal portion of the catheter relative to a proximal portion of the catheter." Claim 39 further recites that the deflecting step is "carried out by sliding the tissue debulking device against a cam surface". This deflecting step is not disclosed or taught by Hundertmark, either alone or in combination with Farr.

In Hundertmark the deflection of the distal portion of the catheter with respect to the proximal portion of the catheter according to the method described in connection with FIG. 11 is caused by the catheter following the curved path of the blood vessel. Specifically, the deflection of the catheter in FIG. 11 of Hundertmark is carried out by advancing the catheter through the curved vessel resulting in the distal end of the catheter being deflected by the wall of the vessel to follow the path of the vessel. The deflection of the distal portion of the catheter is not carried out in the Hundertmark device by any sliding movement of cutter 138 against a cam surface. As a matter of fact, the cam surface which the Examiner points out in the copy of FIG. 11 included in the Office Action appears to be the curved surface of the inner wall of the housing 140. However, the curve

of the inner surface is not created until after the catheter has been deflected. Prior to the catheter being deflected by the vessel wall the curved cam surface to which the Examiner refers does not exist. Clearly, the deflection of the distal portion with respect to the proximal portion of the catheter in FIG. 11 of Hundertmark can not be carried out by cutter 138 sliding against a cam surface when the cam surface does not exist prior to the distal portion of the catheter being deflected. Stated differently, in Hundertmark, deflection of the catheter against the vessel causes movement of the cutter against the cam surface, whereas the claims require that movement of the cutter against the cam surface cause the deflection. Therefore, Hundertmark does not disclose nor teach this element of the claims.

Further, Farr does not disclose or teach a method which includes the step of "deflecting a distal portion of the catheter relative to a proximal portion of the catheter. . . by sliding the tissue debulking device against a cam surface to expose the tissue debulking device through the cutting window". As a matter of fact Farr does not disclose any deflection of the distal portion of the catheter during use. Additionally, the cutting blade in Farr is exposed through a side opening by offsetting a spherical cutter from the axis of the catheter. Since neither Hundertmark nor Farr, alone or in combination, disclose the deflecting step claim 39 is allowable for at least that reason.

This conclusion is consistent with the Examiner's own description of the method disclosed by Hundertmark. Specifically, in describing the deflection of the distal portion of the catheter the Examiner states that "the proximal movement of the catheter through a tortuous blood vessel causes the deflection against an inner cam surface of the catheter". (Office Action, page 2, paragraph 3). Further, the Examiner notes that "the inner surface of the catheter adjacent the location of the cutter acts as a cam surface when the distal end of the catheter is deflected, as shown in Fig. 11." (Office Action, page 4, paragraph 3, emphasis supplied).

Thus, the Examiner acknowledges that the deflection is created or caused by the shape of the vessel and that the cam surface is not created until after the catheter is deflected by the vessel wall. The Examiner does not describe the deflection of the catheter as being caused or carried out by any sliding movement of the cutter. Clearly, the Examiner could not make such a statement since Hundertmark is clear that the catheter deflection results from the tortuous path traversed by the catheter and not from any interaction between the cutter and the wall of the catheter. Thus, even if the Examiner's description of the method is accurate the step of "deflecting a distal portion of the catheter" is carried out by moving the catheter proximally through a tortuous vessel and not by "sliding the tissue debulking device against a cam surface" as required by the claims.

Claim 39 is also allowable for another reason. Claim 39 recites that the debulking step is "carried out by advancing the catheter in the body lumen to move the rotating tissue debulking device and cutting window through material in the body lumen during the debulking step". The Examiner states with respect to claim 39 that Hundertmark is silent with regards to the step of advancing the catheter in the body lumen to move the rotating tissue debulking device and cutting window through material in the deflecting step. The Examiner states, however, that the device shown in FIG. 11 is not secured to the region of stenosis and is capable of being moved through the body lumen of the blood vessel during the cutting process. The Examiner further states that Farr discloses another type of atherectomy device and methods of using the device including the steps of advancing the device through a patient's vascular system while cutting the obstructive tissue (Fig. 1). The Examiner, therefore, concludes that one of ordinary skill in the art at the time the invention was made would modify the methodology of Hundertmark to include the method step of Farr because it has been held that the use of a known technique (the step taught by Farr) to improve

similar devices (the device of Hundertmark) in the same way will yield predictable results. Further, the Examiner states it would be obvious to advance the device along the blood vessel while cutting if the region of stenosis is bigger that the cutting window. Applicants disagree and believe that the Examiner has misinterpreted Hundertmark.

Initially, Applicants submit that the Examiner's conclusion that the device shown in FIG. 11 of Hundertmark is not secured to the region of stenosis is incorrect. FIGS. 10, 11 and 12 show an embodiment of the Hundertmark device. FIGS. 11 and 12 are shown to illustrate use of the device in curved blood vessels. Portions of the distal portion of the device around the cutting window are clearly omitted in FIGS. 11 and 12 to show the position of the cutter within the device. However, as shown in FIG. 10, the device has structure which, although not labeled, corresponds to balloon 126 of FIG. 1. More specifically, Hundertmark describes the inflation of balloon 126 in connection with FIGS. 11 and 12 as follows:

> The balloon is inflated after the catheter 110 is positioned within a blood vessel. When the balloon 126 inflates, the balloon 126 pushes the window 142 of the housing 140 against the internal wall of the blood vessel. Atheroma, for example, are invaginated by the window 142 in this way (see FIGS. 11 and 12).

(Hundertmark, Col. 6, lines 59 to 65)(Emphasis supplied).

Therefore, although the inflated balloon is not shown in FIGS. 11 or 12 the use of a balloon in connection with the embodiment of FIGS. 11 and 12 is clearly described. A person of skill in the art would understand from the entirety of Hundertmark that the device of FIGS. 10 to 12 has a balloon. The person of skill would further understand that inflation of the balloon would cause stenotic material SM to invaginate the window 142 when the device is used to remove SM from either inside or outside curves of vessels as shown in FIGS. 11 and 12.

Therefore, Applicants believe the Examiner has misinterpreted the structure of the embodiment of FIG. 11.

Further, even if the device is capable of being moved through the lumen of the vessel during the cutting process as suggested by the Examiner a person of skill in the art would have no reason to use the Hundertmark device in that manner. The Examiner states that Hundertmark is "silent with regards to the step of advancing the catheter in the body lumen to move the rotating tissue debulking device and cutting window through material in the body lumen". Applicants submit that Hundertmark is not silent on this step. As a matter of fact Hundertmark consistently describes the operation of the device as comprising rotating and axially translating the cutter 138 past the side window 142 to sever and remove stenotic material from an area of interest. (Hundertmark, Col. 6, lines 9 to 14; Col. 10, lines 43 to 50). This is the only way Hundertmark describes the device being used to cut material. In other words, the Hundertmark device is constructed so that once the cutting window has been pushed against the vessel wall to invaginate the window with atheroma the device and window remain in that position and the cutter is advanced past the window to cut the invaginated atheroma.

Applicants also disagree with the Examiner's conclusion that it would be obvious to modify the methodology of Hundertmark to include the method step of Farr. Farr discloses an atherectomy device with a spherically shaped cutter which rotates about an axis that is offset from the axis of the catheter. This results in the cutting blade projecting through an opening in the sidewall of the catheter housing beyond the periphery of the housing. (Farr, col. 4, lines 29 to 33). The cutter is axially fixed and does not translate axially with respect to the housing or the opening in the sidewall of the housing. The cutter of the atherectomy device disclosed in Hundertmark is substantially different. It is generally cylindrical, and

rotates and axially translates with respect to the cutting window so only the cutter, not the cutting window, need be moved during the cutting process. This is significant since in Hundertmark the window is pushed against the vessel wall so that atheroma will invaginate the cutting window and the device is held in that position while the cutter is advanced past the window to cut the atheroma which has invaginated the window. Given these substantial differences there is no reason why a person of skill in the art would look to Farr to modify the method of using the device of Hundertmark in the manner required by claim 39. Specifically, there is no reason why a person of skill in the art would move the cutter and the cutting window of Hundertmark through the atheroma together.

Further, Hundertmark emphasizes the importance of preventing the escape of the cutter through the cutting window (Hundertmark, Col. 4, lines 65 to 67; Col. 9, lines 34 to 43). They disparage prior art devices and methods which do not achieve this goal (Hundertmark, Col. 2, Lines 2 to 7). Clearly Hundertmark teaches away from use of devices such as disclosed in Farr which have outwardly extending cutting blades. Therefore, a person of skill in the art would be directed by Hundertmark away from making this modification.

In view of the foregoing Applicants believe claim 39 is in condition for allowance. Claims 42, 44 to 46 and 48 depend from claim 39 and add further limitations which distinguish over the art and are allowable for at least the same reasons as claim 39.

Independent claims 62 and 69 are directed to methods which include the step of advancing a catheter having a cutter and a window (claim 62) or opening (claim 69) in a distal direction. In claim 62 the advancing step is done while "the cutter and the window maintain their orientation with respect to one another when advancing the catheter". Claim 69 recites that "the cutter and the opening maintaining their orientation with respect to one another when advancing the

catheter". In rejecting claims 62 and 69 the Examiner states that "the modification (to Hundertmark) to include the step of advancing the device through the occlusive material while the cutter is exposed is provided in the rejections to claims 39". Applicants have discussed in detail above in connection with the rejection of claim 39 the reasons why a person of skill in the art would not modify the method of using the device of Hundertmark with the method disclosed in Farr to move both the cutter and the cutting window together through the atheroma. Those remarks are equally applicable to the rejection of claims 62 and 69. Therefore, Applicants believe claims 62 and 69 are allowable for at least those reasons. Claims 70 to 72 and 74 to 76 depend from claim 69 and add further limitations which distinguish over the art and are allowable for at least the same reasons as claim 69.

The Examiner rejected claim 47 under 35 U.S.C. § 103(a) as being unpatentable over Hundertmark in view of Farr and further in view of U.S. Patent No. 5,941,869 to Patterson et al. (Patterson). Claim 47 depends from claim 39 and adds further limitations to distinguish over the art and is allowable for at least the same reasons as claim 39.

Double Patenting

The Examiner provisionally rejected claims 39, 42, 44 to 48, 62, 69 to 72 and 74 to 76 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 to 24 of co-pending Application No. 10/421979 and claims 1 to 15 of co-pending application No. 10/288581. Applicants will address this rejection when the Examiner indicates these claims are allowable.

Examiner's Response to Arguments

In paragraph 8 the Examiner states that "the applicant argued that Hundertmark fails to teach a cam surface." The Examiner goes on to note that in FIG. 11 the illustrated portion of housing 140 "acts as a cam surface once the nose cone 144 has been deflected by the curved passageway of the blood vessel". Applicants have addressed this issue in detail in connection with the rejection of claim 39 above and will not repeat those comments here. However, Applicants will clarify their position with respect to the surface the Examiner has identified as the "cam surface". Applicants recognize that the portion of the catheter wall identified by the Examiner as the cam surface always exists. However, that surface is not curved or cammed until the catheter has been deflected by the vessel wall. How then, can the specific requirement of claim 39 that the step of "deflecting a distal portion of the catheter" be carried out by "sliding the tissue debulking device against a cam surface" be met by the Hundertmark device? It can not.

The Examiner further states in paragraph 8 that the embodiment shown in FIGS. 10 to 12 is a different embodiment from that shown in FIG. 1 and that the only disclosed similarities is the use of a hollow shaft circumscribing a guidewire. Additionally, the Examiner states that the operation of the embodiment shown in FIGS. 10 to 12 do not state that a balloon is used to deflect the cutter. Instead, according to the Examiner the embodiment relies on the natural bends/curve of the blood vessel to deflect the cutter, as shown in FIGS. 11 and 12. Applicants agree that the embodiment shown in FIGS. 10 to 12 is a different embodiment from the one shown in FIG. 1. However, Applicants disagree with the remainder of the Examiner's statements regarding the embodiment of FIGS. 10 to 12. In particular, Applicants submit that Hundertmark specifically describes the use of a balloon

with the embodiment of FIGS. 10 to 12, and refers specifically to FIGS. 11 and 12 in connection with that description. As described above, Hundertmark provides that:

> The balloon is inflated after the catheter 110 is positioned within a blood vessel. When the balloon 126 inflates, the balloon 126 pushes the window 142 of the housing 140 against the internal wall of the blood vessel. Atheroma, for example, are invaginated by the window 142 in this way (see FIGS. 11 and 12).

(Hundertmark, Col. 6, lines 59 to 65)(Emphasis supplied).

This statement coupled with the fact that the structure of the balloon is shown in FIG. 10 clearly supports the conclusion that a balloon is incorporated and used with the embodiment of FIGS. 10 to 12. Therefore, the Examiner's conclusion that the embodiment of FIGS. 10 to 12 relies on the natural bends/curve of the blood vessel "to deflect the cutter" is not consistent with the description of the structure or use of the device by Hundertmark as discussed above.

Based on the foregoing Applicant submits all of the pending claims are in condition for allowance.

It is believed that no fees are due in connection with this submission. However if this is incorrect, please charge any additional fees to Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

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By /Terry L. Wiles/

Customer No. 009561
Terry L. Wiles (29,989)
Patrick J. O'Connell (33,984)
POPOVICH, WILES &
O'CONNELL, P.A.
8519 Eagle Point Blvd., Suite 180
Lake Elmo, MN 55042
Telephone: (651) 330-4780
Attorneys for Applicants
twiles@pwolaw.biz